

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-127V

LINDA FLETCHER,
Petitioner,
v.
SECRETARY OF HEALTH AND
HUMAN SERVICES,
Respondent.

Chief Special Master Corcoran

Filed: August 16, 2023

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Rachelle Bishop, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On February 4, 2020, Linda Fletcher filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges a Table injury - that she suffered a shoulder injury related to vaccine administration (“SIRVA”) after receiving an influenza (“flu”) vaccine in her right shoulder on October 3, 2018. Petition at 1; Ex. 9 at ¶ 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (“SPU”).

¹ Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

After a full review of the evidence, I find it most likely that Petitioner received her October 3, 2018 flu vaccination in her right deltoid or shoulder, suffered the onset of her shoulder pain within 48 hours of October 3, 2018 flu vaccination, and has satisfied all Table requirements for a SIRVA injury, and is otherwise entitled to compensation for her SIRVA.

I. Relevant Procedural History

After the case's initiation and SPU assignment, Respondent filed a Rule 4 Report recommending that entitlement to compensation be denied, because Petitioner has failed to meet two QAI requirements to establish a Table SIRVA injury. ECF No. 23. First, Respondent asserts that the vaccination record indicates that Petitioner received the vaccine in her left shoulder, and therefore it could not be responsible for her *right* shoulder injury. ECF No. 23 at 6. Second, Respondent argues that Petitioner has failed to demonstrate that the onset of her shoulder pain began within 48 hours of vaccination. *Id.* at 6-7.

I therefore set deadlines for the filing of briefs addressing Petitioner's entitlement to compensation. ECF No. 24. On December 20, 2021, Petitioner filed a Motion for Ruling on Record in support of this claim. ECF No. 28. On December 22, 2021, Respondent filed an opposition brief maintaining the arguments set forth in his Rule 4 Report that Petitioner has failed to establish a SIRVA Table claim. ECF No. 30. On December 29, 2021, Petitioner filed a Reply brief. ECF No. 31. This matter is ripe for my resolution.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a

petitioner may present testimony which is “consistent, clear, cogent, and compelling.” *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement,³ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

³ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

III. Relevant Factual Evidence

I have reviewed all evidence filed to date, but limit my discussion below to those items most relevant to the disputed situs and onset questions. 42 C.F.R. § 100.3(c)(10)(ii-iii); 42 C.F.R. § 100.3(a)(XIV)(B).

A. Records

- A Vaccine Administration Record from Publix Pharmacy indicates that Petitioner received a flu vaccine on October 3, 2018. “LA” or left arm, is circled, as the “Site Given.” Ex. 1 at 1. The record is signed, but not dated, by pharmacist, Nichole Guidish. *Id.*
- A separate record, or letter, from Publix Pharmacy, dated July 30, 2020, provides a statement that Petitioner “was administered an influenza vaccination on October 3, 2018. The vaccine was administered in her *right* deltoid.” Ex. 11 (emphasis added). The record is signed by pharmacist, Ryan Padgett. *Id.*
- On November 12, 2018 (approximately six weeks post- vaccination), Petitioner was seen by her primary care provider, Rajneesh K. Bhalla, MD., in a “[f]ollow-up visit for to multiple problems.” Ex. 2 at 10. The record indicates that Petitioner received a flu vaccine two weeks ago, but does not otherwise discuss shoulder pain. *Id.* at 12.
- A separate record, or letter, from Dr. Bhalla dated September 10, 2019, states that Ms. Fletcher, his patient of more than 15 years, “had a [f]lu vaccine on October 3, 2018 at [a] local Publix Pharmacy.” Ex. 5. Dr. Bhalla indicates that Petitioner “was seen in my office on November 12, 2018 and mentioned pain in right shoulder [that] started immediately after the flu injection.” *Id.* Dr. Bhalla explains that

believing her shoulder pain would be “transient,” Petitioner was provided “verbal assurance and supportive treatment.” *Id.*

- On January 24, 2019 (over three and-a-half months following Petitioner’s vaccination), Petitioner was seen again by Dr. Bhalla “for multiple problems.” Ex. 2 at 6. The record indicates that Petitioner was “[c]omplaining of pain in the right shoulder and unable to lift or move the shoulder. Patient correlates since she had flu vaccine at the local pharmacy and developed pain in the right shoulder and restriction in the mo[ve]ment. Symptoms are getting worse.” *Id.* On examination, Petitioner exhibited diminished range of motion in her right shoulder. *Id.* at 7. Petitioner was assessed with right shoulder joint pain and frozen shoulder. She was referred to an orthopedic surgeon. *Id.* at 8.
- On February 4, 2019, Petitioner was returned to see Dr. Bhalla. Dr. Bhalla noted on “review patient did have flu shot last October at the Publix pharmacy and since then she has pain and diminished range of movements on the right shoulder, and correlates to the flu vaccine and mentions she almost cried as she thinks injection was given at wrong place.” *Id.* at 3. Petitioner was again assessed with right shoulder joint pain and frozen shoulder. *Id.* at 4. Petitioner was advised to get an evaluation from an orthopedic surgeon, however she “want[ed] to get physical therapy. *Id.*
- On February 19, 2019, Petitioner underwent a Physical Therapy Initial Examination. Petitioner provided a “History of Present Condition/Mechanism of Injury” as follows: “Patient states that she had a flu shot in her right shoulder [in] October 2018 and it was very painful. She reported it to her Doctor and was told it would resolve on its own but it has not.” Ex. 4 at 51. Petitioner engaged in 24 physical therapy sessions through April 22, 2019. Ex. 6 at 10.
- Thereafter, Petitioner continued to receive treatment for her right shoulder pain – ultimately undergoing right shoulder surgery on August 16, 2019. Ex. 8 at 102.

B. Declarations

Petitioner executed two signed and sworn declarations on February 18, 2020, and December 19, 2021, addressing her vaccination. Exs. 9, 17. In regard to the situs dispute, Petitioner states that she received a flu vaccine at Publix in her right arm on October 3, 2018. Petitioner explains that she received it in her right arm because she previously suffered from cancer in her left breast and had radiation on that side. Ex. 9, ¶ 1; Ex. 17, ¶ 1. Petitioner states that the shot was very painful, and that the following day she could not do anything with her right arm. Ex. 9, ¶ 1. Petitioner indicates that she reported her

shoulder pain to Dr. Bhalla at her November 12, 2018 appointment, but was reassured it would resolve. Ex. 9, ¶ 2. She states when she saw Dr. Bhalla later she again reported that she had “no mobility in [her] right arm and shoulder,” and he referred her for additional treatment. Ex. 9, ¶ 2.

Petitioner also filed signed and sworn declarations from her 49 year-old daughter, Tara Luscavich, and a friend, David Townsend. Exs. 18-19. Ms. Luscavich states that Petitioner “told me that immediately upon receiving the flu shot in her right arm, she had severe shoulder pain and even told the pharmacist.” Ex. 18, ¶ 1. Ms. Luscavich adds that Ms. Fletcher’s pain “intensified in the weeks that followed,” and she recalls her mother “crying on the phone, as she knew something was wrong and she was scared.” *Id.* Mr. Townsend states that he and his wife met with Petitioner “regularly for social events and drinks and always greeted each other with a hug. One evening in October 2018 when I went to hug her, she winched when I touched her right arm. She went on to explain that she had recently had a flu shot at Publix and since the injection she had experienced acute pain in her right arm.” Ex. 19, ¶ 1.

IV. Findings of Fact

A. Situs

The first disputed factor in this case is whether Ms. Fletcher received the flu vaccine in her right shoulder, and therefore her “[p]ain and reduced range of motion are limited to the [right] shoulder in which the intramuscular [flu] vaccine was administered.” 42 C.F.R. § 100.3(c)(10)(ii).

Respondent argues that Petitioner’s vaccine administration record resolves this issue, since the pharmacist circled “LA” - indicating that the situs of Petitioner’s vaccination was her left shoulder. ECF No. 23 at 6. This contention has merit – especially given that the recording of situs here required a specific action (circling) on the vaccine administration record.⁴ But a review of the record in its totality reveals that Petitioner’s contention has preponderant support.

In so finding, I observe that it has often been determined in the Vaccine Program that a vaccine had been administered even though direct documentation was missing, based upon other medical records and/or witness testimony. Certainly witness testimony can be used to overcome the presumption of accuracy often afforded to

⁴ Vaccine administration records with an electronic recording of situs are more easily prone to error. See *Rodgers v. Sec'y of Health & Human Servs.*, No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020).

contemporaneous medical records, if the testimony is “consistent, clear, cogent, and compelling.” *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

Here, two factors favor Petitioner’s version of events. First, the witness statements are persuasive on the *situs* issue. Petitioner’s declarations provide a reasonable explanation for why she would have received her flu vaccination in her right shoulder. As noted above, Petitioner explains that she received the shot in her right (dominant arm) because she previously suffered from cancer in left breast and had radiation on the left side. Ex. 9, ¶ 1; Ex. 17, ¶ 1. In addition, Ms. Luscavich recalls in her sworn declaration that Petitioner “told me that immediately upon receiving the flu shot in her *right* arm, she had severe shoulder pain and even told the pharmacist.” Ex. 18, ¶ 1 (emphasis added).⁵

Second, the medical records in which shoulder pain was discussed consistently report right shoulder pain associated with the vaccination – necessarily implying that she received her vaccination in her right shoulder. Ex. 2 at 3, 6. And when commencing physical therapy on February 19, 2019, Petitioner *did* explicitly report to her physical therapist “that *she had a flu shot in her right shoulder [in] October 2018* and it was very painful. She reported it to her Doctor and was told it would resolve on its own but it has not.” Ex. 4 at 51 (emphasis added).

Taken together as a whole, in this case Petitioner’s cogent explanation in her declarations for why she received her vaccination in her right shoulder, supporting declaration from Petitioner’s daughter, and subsequent contemporaneous treatment records preponderantly demonstrate that Petitioner most likely received her October 3, 2018 flu vaccine in her right shoulder and outweigh her vaccine administration record.

In light of this finding, I also find Petitioner has satisfied the third SIRVA QAI criterion and established her “[p]ain and reduced range of motion [from her flu vaccination] are limited to the [right] shoulder in which the intramuscular vaccine was administered.” 42 C.F.R. § 100.3(c)(10)(iii).

⁵ I acknowledge that Petitioner submitted a letter from a Publix Pharmacy pharmacist, dated July 30, 2020, which provides a statement that Petitioner “was administered an influenza vaccination on October 3, 2018. The vaccine was administered in her right deltoid.” Ex. 11. However, no basis was provided for this statement signed nearly 22 months after Petitioner’s vaccination by a pharmacist other than the one who signed Petitioner’s vaccine administration record. *Id.* Accordingly, I assigned little to no weight to this evidence.

B. Onset

The second disputed factor is whether Petitioner experienced the onset of her pain within 48 hours after her October 3, 2018 vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii).

As Respondent correctly points out, the records corresponding to Petitioner's November 12, 2018 appointment with her primary care provider, Dr. Bhalla – the first after vaccination - fail to document *any* report of shoulder pain. In fact, reports of shoulder pain do not appear in the medical records until Petitioner's next visit with Dr. Bhalla, on January 24, 2019 – more than three months after Petitioner's October 3, 2018 flu vaccination. Ex. 2 at 6.

However, Petitioner's January 24, 2019 record, and subsequent treatment records describing the onset of Petitioner's right shoulder pain, consistently link Petitioner's shoulder pain with or "since" her October 3, 2018 flu vaccine. Ex. 2 at 6 (Dr. Bhalla's January 24, 2019 record stating "[p]atient correlates [her right shoulder pain as] since she had flu vaccine at the local pharmacy and developed pain in the right shoulder and restriction in the mo[ve]ment. Symptoms are getting worse"); Ex. 2 at 3 (Dr. Bhalla's February 4, 2019 record stating on "review patient did have flu shot last October at the Publix pharmacy and since then she has pain and diminished range of movements on the right shoulder, and correlates to the flu vaccine and mentions she almost cried as she thinks injection was given at wrong place"); Ex. 4 at 5 (Petitioner's February 19, 2019 initial PT evaluation recording "[p]atient states that she had a flu shot in her right shoulder [in] October 2018 and it was very painful. She reported it to her Doctor and was told it would resolve on its own but it has not").

Additionally, Dr. Bhalla's signed statement, dated September 2019, indicates that Petitioner did in fact report her shoulder pain at her November 12, 2018 appointment. Ex. 5. Dr. Bhalla states that Petitioner "was seen in my office on November 12, 2018 and mentioned pain in right shoulder [that] started immediately after the flu injection." *Id.* Dr. Bhalla explains that believing Petitioner's shoulder pain would be "transient," Petitioner was provided "verbal assurance and supportive treatment." *Id.* I find Dr. Bhalla's statement regarding the expected "transient" duration of Petitioner's post vaccination pain to be a reasonable explanation for why Petitioner's shoulder pain is not documented in his November 12, 2018 medical record, and is consistent with Petitioner's allegation that Dr. Bhalla stated her pain "would go away" when she reported it at her November 12, 2018 appointment. Ex. 9, ¶ 2. Additionally, both Dr. Bhalla's statement and Petitioner's own declaration are consistent with each other and the history Petitioner provided during her initial PT evaluation that "she had a flu shot in her right shoulder [in] October 2018

and it was very painful. She reported it to her Doctor and was told it would resolve on its own but it has not." Ex. 4 at 51. The third-party witness declarations are consistent with Table onset allegations as well. See Exs. 18-19.

The Vaccine Act specifically contemplates that in some cases a special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). The Act elaborates that "[s]uch a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

In sum, while the most immediately-contemporaneous records (Dr. Bharra's November 12, 2018 records) do not support a finding of Table onset, those records are outweighed (and outnumbered) by the consistent onset histories contained in Petitioner's subsequent treatment records – the most persuasive of which – are collectively dated within five months of Petitioner's October 3, 2018 vaccination. Ex. 13 at 3, 13; Ex. 14 at 6; Ex. 15 at 8, 11. Onset in these later records is further corroborated by the signed statement of Dr. Bharra, and the declarations of Petitioner and two other witness declarations offered in support of Petitioner's case. The fact that several of these treatment-related records were generated within five months of vaccination is also relevant to this inquiry; this is not a case where a petitioner relies on records long after the immediate timeframe to prove onset.

Thus, the totality of the evidence preponderantly supports the conclusion that Petitioner's shoulder pain occurred within 48 hours of her vaccination, and likely began the same day – October 3, 2018 – that her vaccination was administered, meaning the Table onset requirement has been satisfied. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii). However, if it becomes necessary for me to determine damages in this matter, I will take into consideration the fact that Petitioner's shoulder pain is not documented in her contemporaneous medical records until *more than three months following her vaccination* – indicating that Petitioner's shoulder pain (even if most likely reported to Dr. Bharra, approximately six weeks after her vaccination, on November 12, 2018) was not severe enough to warrant mention close-in-time to vaccination, or to compel Petitioner to make an earlier medical appointment to address her shoulder pain.

C. Other Table Requirements and Entitlement

Petitioner has established all other requirements for a Table SIRVA claim. There is no history of shoulder pain, inflammation, or dysfunction that would explain the post-vaccination injury. 42 C.F.R. § 100.3(c)(10)(i). Additionally, there is not preponderant evidence of another condition that would explain the symptoms. 42 C.F.R. § 100.3(c)(10)(iv). However, even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, residual effects of injury lasting six months, *etc.* See *generally* § 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed in this claim. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master